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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/031,154	04/24/2002	George N. Cox III	4152-3-PUS	6320

22442 7590 03/08/2005

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EXAMINER	
LOCKARD, JON MCCLELLAND	
ART UNIT	**PAPER NUMBER**
1647	

DATE MAILED: 03/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/031,154	COX ET AL.	
	Examiner	Art Unit	
	Jon M Lockard	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 April 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10,12 and 14-61* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-10,12 and 14-61* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-10, 12, 14-33 and 37-61, drawn to fusion proteins, nucleic acids encoding said fusion proteins and vectors and host cells comprising the same, and methods of producing and purifying said fusion proteins.

Group II, claim(s) 34-36, drawn to methods of treatment comprising administering a fusion protein.

2. The inventions listed as Groups I-II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Group I is directed to a fusion protein comprising a soluble protein joined without an intervening peptide linker to an immunoglobulin (Ig) domain, wherein the soluble protein is selected from the group consisting of a growth factor, a cytokine that is not IL-10, and wherein the immunoglobulin does not contain a variable region. However, since Gayle et al. (U.S. Pat. No. 5,576,191) teaches soluble ST2 ligand (ST2 is an IL-1 receptor-like protein also referred to as T1, Fit-1, or DER4) joined without an intervening peptide linker to the Fc portion of a human IgG1 antibody, no special technical feature exists for Group I as defined by PCT Rule 13.2, because it does not define a contribution over the prior art. Because the technical feature of Group I is not a special technical feature, and because the technical features of the Group II invention is not present in the Group I claims, unity of invention is lacking.

3. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

In Groups I and II, species (1) is Growth hormone, species (2) is GM-CSF, species (3) is Il-11, species (4) is TPO, species (5) is SCF, species (6) is flt3, species (7) is prolactin, species (8) is placental lactogen, species (9) is IL-2, species (10) is IL-3, species (11) is IL-4, species (12) is IL-5, species (13) is IL-6, species (14) is IL-7, species (15) is IL-9, species (16) is IL-10, species (17) is IL-11, species (18) is IL-12 (p35 subunit), species (19) is IL-13, species (20) is IL-15, species (21) is oncostatin M, species (22) is ciliary neurotrophic factor, species (23) is leukemia inhibitory factor, species (24) is alpha interferon, species (25) is beta interpheron, species (26) is gamma interferon, species (27) is omega interferon, species (28) is tau interferon, species (29) is G-CSF, species (30) is cardiotrophin-1, species (31) is macrophage colony stimulating factor, and species (32) is EPO.

4. Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

5. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

6. The claims are deemed to correspond to the species listed above in the following manner:

Species (1): Claims 12, 16, 22-23, 41, 50, 56, and 61
Species (2): Claims 14, 16, 21-23, 51, 56, and 61

Species (3): Claims 16, 21-23, 25, 41, 51, 56, and 61
Species (4): Claims 14, 16, 21-23, 41, 51, 56, and 61
Species (5): Claims 14, 16, 21-23, 41, 51, 56, and 61
Species (6): Claims 14, 16, 21-23, 41, 51, 56, and 61
Species (7): Claims 16, 22-23, 37, 41, and 61
Species (8): Claims 16, 22-23, 41, and 61
Species (9): Claims 16, 22-23, 41, and 61
Species (10): Claims 16, 22-23, 41, and 61
Species (11): Claims 16, 22-23, 41, and 61
Species (12): Claims 16, 22-23, 41, and 61
Species (13): Claims 16, 22-23, 41, and 61
Species (14): Claims 16, 22-23, 41, and 61
Species (15): Claims 16, 22-23, 41, and 61
Species (16): Claims 16, 22-23, 41, and 61
Species (17): Claims 16, 22-23, 41, and 61
Species (18): Claims 14, 16, 22-23, 41, and 61
Species (19): Claims 16, 22-23, 41, and 61
Species (20): Claims 16, 22-23, 41, and 61
Species (21): Claims 16, 22-23, 41, and 61
Species (22): Claims 16, 22-23, 41, and 61
Species (23): Claims 16, 22-23, 41, and 61
Species (24): Claims 16, 22-23, 39, 41, 56, and 61
Species (25): Claims 16, 22-23, 39, 41, 56, and 61
Species (26): Claims 16, 22-23, 39, 41, 56, and 61
Species (27): Claims 16, 22-23, 39, 41, and 61
Species (28): Claims 16, 22-23, 39, 41, and 61
Species (29): Claims 8-10, 16-18, 22-23, 25, 35, 41, 47-49, 53-55, and 61
Species (30): Claims 16, 22-23, 41, and 61
Species (31): Claims 16- 22-23, 41, and 61
Species (32): Claims 19-20, 22-23, 25, 28, 36, 40-41, 44, 53, 57-59, and 61

The following claim(s) are generic: 1-7, 15, 24, 26-34, 37, 42-43, 45-46, and 52.

7. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: Each species of fusion protein listed above represents a structurally and functionally different chemical compound from each other, which

can be made and used without the other compounds. Lack of unity is shown because these compounds and methods lack a common utility which is based upon a common structural feature which has been identified as the basis for that common utility.

Rejoinder Under Ochiai/Brouwer

8. The Examiner has required restriction between product and method claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn method claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Method claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

9. In the event of rejoinder, the requirement for restriction between the product claims and the rejoined method claims will be withdrawn, and the rejoined method claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and method claims may be maintained. Withdrawn method claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to

retain the right to rejoinder in accordance with the above policy, Applicant is advised that the method claims should be amended during prosecution either to maintain dependency on the method claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

10. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the Examiner before the patent issues. See MPEP § 804.01.

11. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

12. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Jon M. Lockard, Ph.D.** whose telephone number is **(571) 272-2717**. The examiner can normally be reached on Monday through Friday, 8:00 AM to 6:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Brenda Brumback, Ph.D.** can be reached on **(571) 272-0961**.

The fax number for the organization where this application or proceeding is assigned is **571-273-8300**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see **http://pair-direct.uspto.gov**. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **866-217-9197** (toll-free).

JML
February 28, 2005

LORRAINE SPECTOR
PRIMARY EXAMINER